



TPW

1648

Attorney Docket No. 2302-16464 (PP16464.004)

PATENT

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By:

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of VAJDY et al.

Serial No.: 10/051749

Examiner: T. Brown

Confirmation No.: 5494

Art Unit: 1648

Filed: January 14, 2002

For: NUCLEIC ACID MUCOSAL IMMUNIZATION

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Enclosed is an Information Disclosure Statement and accompanying Form PTO/SB/08A for the above-identified patent application.

- In accordance with 37 C.F.R. §1.97(b), no additional fee for submission of the IDS is required.
- In accordance with 37 C.F.R. §1.97(c), also enclosed is:
  - the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p); or
  - a statement as specified in 37 C.F.R. §1.97(e).
- In accordance with 37 C.F.R. §1.97(d), a statement as specified in 37 C.F.R. § 1.97(e) and the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) are also enclosed.
- Check No. \_\_\_ in the amount of \$\_\_\_ for the total fee is attached.

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The Commissioner is hereby authorized to charge any appropriate fees under 37  
C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any  
overpayment, to Deposit Account No. 18-1648.

Dated: 5-10-04

Respectfully submitted,

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By:

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Attorney Docket No. 2302-16464 (PP16464.004)

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By: D. M. Hall

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97(b)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,  
Applicant(s) hereby submits the following information in conformance with 37 C.F.R.  
§§1.97 and 1.98.

- [x] Pursuant to 37 C.F.R. §1.98, copies of documents cited in the attached Form PTO/SB/08 are enclosed.
- [ ] No copies of publications \_\_\_\_\_ listed on the attached Form PTO/SB/08A are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. \_\_\_\_ to which the above-identified application claims priority under 35 U.S.C. §120.
- [ ] No copies of publications \_\_\_\_\_ are being provided pursuant Office waiver of 37 C.F.R. §1.98(a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003.

- Publication(s) \_\_\_\_\_ listed on the attached Form PTO/SB/08A were cited in a foreign search or examination report corresponding to \_\_\_\_\_ application serial no. \_\_\_\_\_ and mailed on \_\_\_\_\_.
- Enclosed is a copy of a non-English publication(s) \_\_\_. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
- Enclosed is a copy of a non-English publication(s) \_\_\_. English language publication \_\_\_ (copy enclosed) claims priority from this non-English publication.
- Enclosed is an explanation of non-English publication(s) \_\_ for which an English translation is not available.
- Enclosed is an English translation of non-English publication(s) \_\_ cited in the attached Form PTO/SB/08A.
- Enclosed is a copy of pending patent Application Serial No. \_\_\_\_.

This Information Disclosure Statement is filed within any one of the following time periods:

- within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- before the mailing date of a first office action on the merits; or
- before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08A to the undersigned.

Dated: 5-10-04

Respectfully submitted,

Chiron Corporation  
Intellectual Property – R440  
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Dahna S. Pasternak  
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Reg. No. 41,411



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PTO/SB/08A (08-00)

<p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>				<i>Complete if Known</i>		
Sheet		1	of	4	Attorney Docket Number	2302-16464 (PP16464.004)
					Application Number	10/051749
					Filing Date	January 14, 2002
					First Named Inventor	Vajdy et al.
					Group Art Unit	1648
					Examiner Name	T. Brown

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

<sup>2</sup> See attached Kinds of U.S. Patent Documents.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
Sheet	2	of	4	Application Number	10/051749
				Filing Date	January 14, 2002
				First Named Inventor	Vajdy
				Group Art Unit	1648
				Examiner Name	T. Brown
				Attorney Docket Number	2302-16464 (PP16464.004)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	CA	BAGARAZZI et al., "Systemic and Mucosal Immunity is Elicited after Both Intramuscular and Intravaginal Delivery of Human Immunodeficiency Virus Type 1 DNA Plasmid Vaccines to Pregnant Chipanzees", <i>J. Infect. Dis.</i> (1999), <u>180</u> : 1351-1355.	
	CB	BARRE-SINOSSI et al., "Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)", <i>Science</i> (1983), <u>220</u> (4599): 868-871.	
	CC	BELYAKOV et al., "Induction of a mucosal cytotoxic T-lymphocyte response by intrarectal immunization with a replication-deficient recombinant vaccinia virus expressing human immunodeficiency virus 89.6 envelope protein", <i>J. Virol.</i> (1998), <u>72</u> (10): 8264-8272.	
	CD	BELYAKOV et al., "The Importance of Local Mucosal HIV-Specific CD8+ Cytotoxic T Lymphocytes for Resistance to Mucosal Viral Transmission in Mice and Enhancement of Resistance by Local Administration of IL-12.", <i>J. Clin. Invest.</i> (1998), <u>102</u> (12): 2072-81.	
	CE	CAIRNS et al., "New Viral Vectors for HIV Vaccine Delivery.", <i>Aids Research and Human Retroviruses</i> (Mary Ann Liebert, ed., US) (1998), <u>14</u> (17): 1501-1508.	
	CF	CALEY et al., "Humoral, Mucosal, and Cellular Immunity in Response to a Human Immunodeficiency Virus Type 1 Immunogen Expressed by a Venezuelan Equine Encephalitis Virus Vaccine Vector.", <i>J. Virol.</i> (1997), <u>71</u> (4): 3031-3038.	
	CG	CLAVEL et al., "Isolation of a New Human Retrovirus from West African Patients with AIDS.", <i>Science</i> (1986), <u>233</u> : 343-6.	
	CH	CLAVEL et al., "Molecular Cloning and Polymorphism of the Human Immune Deficiency Virus Type 2", <i>Nature</i> (1986), <u>324</u> : 691-695.	
	CI	GARDNER et al., "Infection of Human Dendritic Cells by a Sindbis Virus Replicon Vector Is Determined by a Single Amino Acid Substitution in the E2 Glycoprotein.", <i>J. Virol.</i> (2000), <u>74</u> (24): 11849-11857.	
	CJ	GUYADER et al., "Genome Organization and Transactivation of the Human Immunodeficiency Virus Type 2", <i>Nature</i> (1987), <u>326</u> : 662-669.	
	CK	HARIHARAN et al., "DNA Immunization against Herpes Simplex Virus: Enhanced Efficacy Using a Sindbis Virus-Based Vector.", <i>J. Virol.</i> (1998), <u>72</u> (2): 950-958.	

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				Filing Date	January 14, 2002
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				Examiner Name	T. Brown
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	CL	KANO et al., "Induction of SIV-specific immune responses by using recombinant sendai viral vector.", <i>7<sup>th</sup> Conference on Retroviruses and Opportunistic Infections</i> , [Online] 30 January 2000 – 2 February 2000, retrieval from the Internet: <URL: <a href="http://www.retroconference.org/2000/abstracts/807.htm">http://www.retroconference.org/2000/abstracts/807.htm</a> >, abstract 807 [retrieved on 2004-01-28].		
	CM	LEVY et al., "Isolation of Lymphocytopathic Retroviruses from San Francisco Patients with AIDS", <i>Science</i> (1984), <u>225</u> (4664): 840-842.		
	CN	POLO et al., "Stable alphavirus packaging cell lines for Sindbis virus- and Semliki Forest virus-derived vectors.", <i>PNAS USA</i> (1999), <u>96</u> : 4598-4603.		
	CO	POPOVIC et al., "Detection , Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and Pre-AIDS.", <i>Science</i> (1984), <u>224</u> (6468): 497-500.		
	CP	STAATS et al., "Intranasal Immunization is Superior to Vaginal, Gastric, or Rectal Immunization for the Induction of Systemic and Mucosal Anti-HIV Antibody Responses", <i>AIDS Res Hum Retroviruses</i> (1997), <u>13</u> (11): 945-952.		
	CQ	TSUJI et al., "Recombinant Sindbis Viruses Expressing a Cytotoxic T-Lymphocyte Epitope of a Malaria Parasite or of Influenza Virus Elicit Protection Against the Corresponding Pathogen in Mice.", <i>J. Virol.</i> (1998), <u>72</u> (8): 6907-10.		
	CR	VAJDY et al., "Human Immunodeficiency Virus Type 1 Gag-Specific Vaginal Immunity and Protection After Local Immunizations with Sindbis Virus-Based Replicon Particles.", <i>J. of Infect. Diseases</i> (2001), <u>184</u> : 1613-1616.		
	CS	VAJDY et al., "Potent mucosal HIV-1 specific immunity and protection from vaginal viral challenge following mucosal immunizations with non-replicating Sindbis virus-based particles.", <i>FASEB J.</i> (2001), <u>15</u> (5): A1192.		
	CT	VILLACRES et al., "Maintenance of CD8+ T-Cell Memory Following Infection with Recombinant Sindbis and Vaccinia Viruses", <i>Virology</i> (2000), <u>270</u> : 54-64.		

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	CU	VILMER et al, "Isolation of New Lymphotropic Retrovirus from Two Siblings with Haemophilia B, One with Aids", <i>The Lancet</i> (1984), pages 757.		
	CV	WANG et al., "Mucosal Immunization with a DNA Vaccine Induces Immune Responses Against HIV-1 at a Mucosal Site", <i>Vaccine</i> (1997), 15(8): 821-825.		

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